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The Surgical Management of Acute Limb Ischaemia due to Native Vessel Occlusion

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Objectives: *data from the STILE study have indicated that for patients with subacute limb ischaemia due to native vessel occlusion, surgery is both more effective and durable than thrombolysis. The purpose of this study was to evaluate the outcome of an aggressive surgical approach in patients presenting with acute limb-threatening ischaemia.*
Design: *details of patients presenting with salvageable acute limb ischaemia due to native artery occlusion over a 6-year period in a University hospital vascular unit setting were obtained from the vascular audit and the outcome of the surgical management of these patients was analysed.*
Results: *one hundred and seventy-four consecutive patients underwent surgery for acute native vessel limb ischaemia (76% lower, 24% upper limb). Fogarty thrombectomy or embolectomy was initially performed in 153 (89%) patients. Of these, 37 (24%) immediately underwent a further procedure: 28 (18%) had on-table thrombolysis and 14 (9%) underwent vascular reconstruction. Twenty-six patients (15%) underwent further limb salvage surgery within 30 days. Life table analysis demonstrated a limb salvage rate of 88% and 76% at 30 days and 2 years, respectively. Patient survival was 75% and 48% at the same time intervals.*
Conclusions: *these results demonstrate that a role for aggressive surgical intervention still exists, resulting in high limb salvage rates.*

Introduction

The recently reported results of the STILE investigators that focused on patients with non-embolic native arterial occlusions demonstrated superior results at 1 year in those patients managed initially by surgery rather than thrombolysis.[1] These data, obtained by prospective randomised study, have provided a fresh challenge to proponents of the use of thrombolytic agents in various forms for the primary treatment of acute limb ischaemia.[2–5] For many surgeons operative intervention remains the "gold standard" of treatment, particularly in the case of acute native vessel occlusion with neurological signs. Nonetheless, in this setting surgery itself has been previously documented to have a mortality rate 20–30%,[6–8] with a limb salvage rate that may not exceed 60%,[6,9] and these quoted figures have provided compelling reasons to consider an alternative approach.

The purpose of this study therefore was to review the outcome of surgery for acute limb-threatening ischaemia in order to question to what extent an aggressive policy of surgical intervention could be sustained in view of reported results of thrombolysis.

Patients and Methods

The details of all patients admitted to the Vascular Unit at the Leicester Royal Infirmary with acute limb-threatening ischaemia over a 6-year period from 1989 were obtained from the computerised vascular audit, and the case notes were reviewed. Acute ischaemia was defined according to recommendations of the *ad hoc* committee on reporting standards of the Society for Vascular Surgery/North American Chapter, International Society for Cardiovascular Surgery.[10] Patients with ischaemic limbs not thought to be salvageable were excluded, as were patients with occlusive events after trauma or previous arterial reconstruction.

Over this period the management policy for patients referred with acute limb ischaemia was as follows. Immediate preoperative imaging was

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obtained when possible, either by employing arteriography, or, from 1994, colour-duplex ultrasonography, particularly when *in situ* thrombosis was suspected. Patients were then taken to theatre and underwent initial embolectomy/thrombectomy through appropriate vessels unless imaging dictated otherwise. For the lower limb this was generally done through a femoral artery approach, for the upper limb through a brachial artery approach. Following successful embolectomy, routinely determined by on-table completion arteriography, as well as clinically by the appearance of the foot (or hand) on closing the arteriotomy, an intravenous infusion of heparin was then begun and warfarin introduced after 2–3 days. Local anaesthesia was preferentially employed in the presence of known cardiopulmonary disease.

In cases where inflow could not be restored by passing the Fogarty embolectomy balloon, an inflow revascularising procedure was immediately carried out, if possible by ilio- or femorofemoral crossover grafts. In cases with adequate inflow, where embolus or thrombus was not retrieved from the distal arterial tree, or when the Fogarty catheter would not pass due to vessel occlusion, on-table arteriography was employed to define a distal vessel suitable for receiving a graft, and immediate reconstruction was performed. If no continuous vessel was revealed, on-table thrombolysis was employed.[11] One hundred thousand units of streptokinase in 100 ml of normal saline were continuously infused intra-arterially over 30 min, into either the exposed popliteal or most suitable crural artery, with an occlusive clamp applied proximally. Arteriography was then repeated and arterial reconstruction was performed when indicated. If a partial improvement was observed a further 100 000 units of streptokinase was given over 30 min with arteriography then repeated.

Patients were taken back to theatre postoperatively if the limb was not deemed salvaged, for fasciotomy, further embolectomy/thrombectomy, vascular reconstruction or for amputation.

Statistical analysis

Median and range were used for descriptive data. Comparisons of proportions were performed using the Chi-squared test with Pearson's correction. Life table analysis was used to determine 30-day and 2-year limb salvage and mortality. This was performed using the Statistical Package for the Social Sciences (SPSS, Chicago, Illinois, U.S.A.).

Results

Patient details

Over the time period of study 174 patients, median age 74 (range: 29–92), of whom 89 (51%) were male, were admitted with native vessel limb-threatening ischaemia thought to be salvageable. One hundred and thirty-two (76%) had lower limb ischaemia (total number of limbs = 145) whilst 42 (24%) had upper limb ischaemia (total number of limbs = 42). Twenty-five (14%) of patients were diabetic, 72 (41%) had documented ischaemic heart disease, whilst 28 (16%) had had a previous cerebrovascular event. By New York Heart Association (NYHA) functional criteria, 36% were identified as Class 3 or 4.† A possible source of embolism was identified in 107 (61% of cases). Preoperative imaging was performed in 48 (36%) of patients presenting with acute lower limb ischaemia, representing 60% of cases where *in situ* thrombosis was suspected clinically.

The median duration of ischaemia was 14 h (range: 1–336); 47% presented with a history of 12 h or less. In cases of lower limb acute ischaemia, the femoral pulse was absent in 32%. One hundred and thirty-five limbs (78%) had a peripheral neurological deficit on presentation (upper limb: 72%; lower limb: 80%).

Operative details

Initial embolectomy or thrombectomy was performed in 153 (89%) cases (see Table 1). Local anaesthesia was used in 90 (52%) of these cases (upper limb: 88%; lower limb: 40%); the limb was initially considered to have been salvaged in 118 (76%) cases. A further intervention was performed after unsuccessful embolectomy/thrombectomy in the remaining 37 (24%) of cases. The details of these interventions is shown in Table 2. Fourteen patients (9%) thus underwent a simultaneous vascular reconstructive procedure. Of patients who underwent on-table lysis there was radiological evidence of improvement in 67% cases; this was significantly more likely to result in limb salvage compared to its use where there was no such improvement (Chi-squared = 7.83, d.f. = 2, $p<0.02$). There were no complications that were attributed to the use of on-table thrombolysis.

Twenty-six patients (15%) were taken back to theatre

† NYHA score, a measure of cardiopulmonary debility according to the degree of symptoms of angina and/or dyspnoea. Class 1 = no symptoms; Class 2 = symptoms with more than usual activity; Class 3 = symptoms with usual activity; Class 4 = symptoms at rest.

Table 1. Nature of initial intervention in patients with acute native artery occlusion.

	Lower-limb	Upper-limb	Total
Initial embolectomy/thrombectomy	112 (86%)	41 (100%)	153 (89%)
Immediate limb salvage	77 (68%)	33 (79%)	110 (71%)
Immediate vascular reconstruction			21 (11%)
Aortobifemoral graft	3		
Ilio/femorofemoral cross over	4		
Iliofemoral graft	1		
Femoroprofunda graft	2		
Femoropopliteal graft	3		
Femorocrural graft	6		
Poplitealcrural graft	1		
Patch-plasty	1		
Carotid subclavian graft		1	

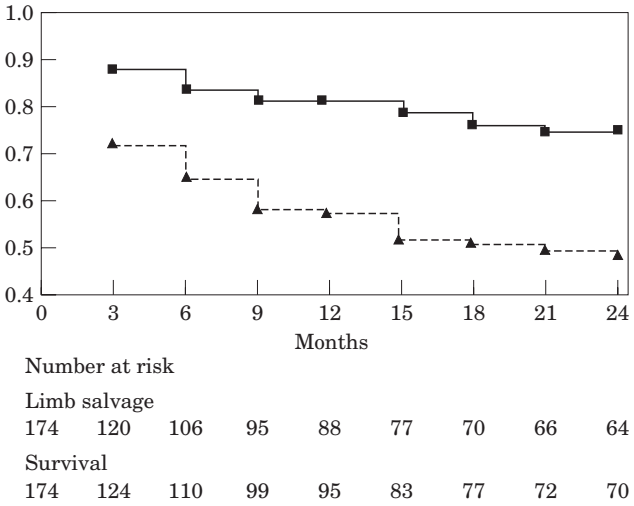

Fig. 1. Limb salvage and survival following surgery for acute limb ischaemia.

for further limb salvage surgery. Of these, 14 underwent further embolectomy/thrombectomy whilst five underwent fasciotomy and seven underwent vascular reconstruction. No early (<30-day) graft occlusions occurred in patients who had not undergone preoperative imaging. Nineteen patients (9%) underwent amputation as a result of failed limb salvage in the first 30 days.

Outcome details

Follow-up data was available in 98% of cases for a median time period of 26 months (range: 0–104 months). Life table analysis (Fig. 1) showed the 30-day limb salvage to be 88% (lower limb alone: 88%; upper limb alone: 95%), whilst the 30-day mortality was 25% (lower limb alone: 26%; upper limb alone: 21%). At 2 years the corresponding limb salvage was 76% (lower limb: 74%; upper limb: 88%) and the survival was 48% (lower limb: 49%; upper limb: 44%).

Sub-group analysis

Sub-group analysis identified particular risk factors. Thus patients with an NYHA grade of III or IV had a significantly higher 30-day mortality than those with an NYHA grade of I or II (Chi-squared = 5.282, d.f. = 1, $p<0.03$), whilst in patients with lower limb ischaemia the 30-day mortality was significantly higher in patients presenting with aortoiliac compared to more distal occlusion (Chi-squared = 8.08, d.f. = 1, $p<0.005$). Whilst the mortality in patients presenting with neurological signs was higher than those without (28% vs. 17%), it did not reach statistical significance. The duration of symptoms time did not appear to be a risk factor, nor was the presence of a previous history of claudication. Use of local anaesthetic did not affect the 30-day mortality.

Discussion

The introduction and development of endoluminal catheter-directed intra-arterial thrombolytic techniques has thrown into question the optimum management of patients with acute limb ischaemia. Whilst many uncontrolled series have shown that thrombolysis can be both effective and safe,[3–5] there have been few prospective randomised studies comparing surgery with thrombolysis in limb ischaemia.[1,12,13] In the only multicentre (TOPAS) study[12] focusing specifically on the use of the two modalities for the treatment of acute limb ischaemia, there were no demonstrable differences in either limb salvage or 1-year survival. This study was subject to limitations, in

Table 2. Nature of additional intervention after failed embolectomy/thrombectomy in 37 patients (six patients had both on-table lysis and vascular reconstruction).

Type of intervention	Number performed
On-table intra-arterial thrombolysis	28 (18%)
Vascular reconstruction:	
Aortobifemoral graft	2
Axillobifemoral graft	1
Iliofemoral or femorofemoral graft	5
Endarterectomy	1
Femoropopliteal graft	3
Femorocrural graft	1
Axillobrachial graft	1

particular that 40% of patients studied presented with graft rather than native vessel occlusion. Furthermore as a Phase I study primarily directed at evaluating a dose range of urokinase, only 58 of 213 patients included were randomised to surgery. Weaver *et al.* reporting for the STILE investigators have recently concluded that in 237 patients with subacute symptoms attributable to non-embolic native artery occlusions randomised to surgery or thrombolysis, surgery was both more effective and durable.[1] However, in this study the median duration of symptoms was 59 days; only 14% of patients in this series presented with ischaemia of less than 14 days' duration.

The present study showed that a surgical approach for the acutely ischaemic limb resulted in a limb salvage rate of 88% at 30 days and 76% at 2 years, which compares favourably with other series, both surgical[14] and thrombolytic,[5] especially when considering the high proportion of patients with neurological signs (80% of patients presenting with lower limb ischaemia), which is known to affect limb salvage.[7] This approach was based on a readiness to proceed to immediate vascular reconstruction with the use of on-table thrombolysis when necessary in the event of failed embolectomy/thrombectomy. Although much emphasis has been placed on the importance of making a diagnostic distinction between *in situ* thrombosis and embolism, the results of our practice, in keeping with that of Hickey *et al.*,[14] indicate that this is not essential provided immediate further action is taken if embolectomy/thrombectomy proves inadequate. Nonetheless, our finding that this situation is realised nearly 30% of the time confirms the usefulness of preoperative imaging: 31% of our patients who underwent arteriography or duplex ultrasonography underwent primary vascular reconstruction. Overall, these figures provide strong evidence for the desirability of patients with acute limb ischaemia to be managed by experienced vascular surgeons.[15]

The use of on-table thrombolysis is a valuable adjunct to limb salvage surgery for acute ischaemia.[11] In our experience, on-table thrombolysis was used in 28 (18%) cases of acute lower limb ischaemia, and was felt to have resulted in a radiological improvement in 16 (67%) of these cases, when it significantly increased the likelihood of limb salvage. This additional therapeutic option is simple and safe and should be considered before attempts at limb salvage are abandoned. We have not found the combination of on-table lysis with fasciotomy to cause clinically significant bleeding problems.

The high mortality of patients presenting with acute limb ischaemia has for a long time been a matter of concern to vascular surgeons and represents one of the driving forces for the development of alternative therapies. The previously reported 20–30% 30-day mortality[6–8,16] was repeated in this study. This high mortality rate reflects the overall precarious medical condition of many of these patients; it is likely that in many cases the presentation as acute ischaemia is an effect rather than a cause of catastrophic systemic circulatory failure. Sub-group analysis has identified predictable particular risk groups. Thus, patients with NYHA grades of III or IV as well as patients with a history of recent myocardial infarction are known to have a high mortality.[7,16,17] Our results indicated that the severity of ischaemia also affects mortality, which has been noted elsewhere.[7,8] In this series this was reflected in the significantly higher mortality in patients presenting with aortoiliac occlusion compared to more distal occlusion, as well as a trend of a higher mortality in patients presenting with neurological signs. This finding is of relevance when evaluating reports of thrombolysis which frequently include patients with presenting with more distal vessel occlusion with a lower incidence of neurological deficit,[5,13] and comparative remarks about 30-day mortality in patients undergoing thrombolysis are probably inappropriate except in the context of randomised studies.

In conclusion, these results have demonstrated that a surgical approach to the management of severe limb ischaemia can achieve a high rate of limb salvage, although with a significant mortality. However, further prospective randomised studies are required to establish whether catheter-directed thrombolysis can achieve as good results with a lower mortality in patients presenting with severe acute limb ischaemia. Given the disparate composition of this patient group, inclusion and exclusion criteria must be carefully scrutinised.

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